

Q Can I bill Medicare and Medicaid for Stim Products that I purchased and prescribed to my patients?

A No. Both the Federal Ethics in Self-Referrals Law (42 U.S.C. § 1395nn), which is commonly known as the “Stark Law” or “physician self-referral ban,” as well as the Medicare Supplier Standards effectively prohibit a physician from seeking reimbursement for DME, including Stim Products, dispensed to Medicare or Medicaid patients. Physicians risk significant fines and penalties by billing Medicare or Medicaid for DME items.

The Centers for Medicare and Medicaid Services (CMS), which is the federal agency charged with administration, oversight, and enforcement of the Stark Law, issued the following statement in connection with the Stark Law regulations:

“There are few, if any, situations in which a referring physician would personally furnish DME and supplies to a patient, because doing so would require that the physician himself or herself be enrolled in Medicare as a DME supplier and personally perform all of the duties of a supplier as set forth in the supplier standards in §424.57(c).

DME suppliers are entities that provide services under the specific Part B benefit for the provision of medical equipment and supplies for use in the patient's home. These entities must be enrolled with the appropriate Medicare contractor as a DME supplier and must meet all of the professional supplier standards and quality standards that we require through regulations and administrative or program instructions. **The enrollment requirements and professional supplier standards are not waived in those situations in which a physician furnishes DME directly to the patient. The services to be personally performed by the physician would include, but not be limited to, the following, as appropriate:**

- Personally fit the item for the beneficiary
- Provide necessary information and instructions concerning use of the DME

- Advise the beneficiary that he or she may either rent or purchase inexpensive or routinely purchased DME
- Explain the purchase option for capped rental DME
- Explain all warranties
- (Usually) deliver the DME to the beneficiary at home
- Explain to the beneficiary at the time of delivery how to contact the physician in his or her capacity as a DME supplier by telephone

A referring physician claiming to provide DME personally would need to maintain adequate documentation to establish that the physician personally performed these and other required DME supplier activities. **All of these supplier requirements would need to be satisfied in order for a physician to be considered to be providing personally DME items and supplies. This is true for all DME furnished by a physician, including, for example, continuous positive airway pressure (CPAP) equipment. We believe that it is highly unlikely that a referring physician would meet the criteria for personally performed services when dispensing CPAP or other DME equipment.”**
72 Fed. Reg. 51012, 51019-51020 (Sep. 5, 2007) (emphasis added).

Physicians who violate the Stark Law are subject to very serious fines and penalties, including exclusion from federal health care programs and collateral liability under the Civil False Claims Act.

For these reasons, Orthofix strongly recommends that physicians NOT bill Medicare or Medicaid for Stim Products.

As you can see, physician billing for DME, including Stim Products, can be complicated. As a result, we recommend that you discuss any billing arrangement with your legal counsel.



Physio-Stim
Bone Growth Stimulator



Cervical-Stim
Bone Growth Stimulator



Spinal-Stim
Bone Growth Stimulator

For more information, contact your local representative or call Orthofix Customer Service at 800-535-4492

www.orthofix.com
www.bonestimulation.com
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Physician Billing for Bone Growth Stimulators

Frequently Asked Questions

As a product-related educational service for our customers, Orthofix has assembled this brief FAQ to relay general information related to a physician or physician group’s billing for bone growth stimulators, including the Orthofix Physio-Stim®, Spinal-Stim® and Cervical-Stim® bone growth stimulators. The information provided below applies to all external bone growth stimulation devices (hereinafter referred to as “Stim Products”) available on the market from any manufacturer.

This FAQ is intended for educational and informational purposes only. It is not intended to be, nor should it be construed as, legal advice. Orthofix makes no representations and expressly disclaims any and all warranties, whether express or implied, including any warranty or representation relating to whether any of the Stim Products are reimbursable by any third party. Likewise, you and/or your physician group are responsible for the accurate and complete coding and billing of any and all third-party claims. Orthofix recommends that you contact an experienced health care attorney to discuss any specific questions or for advice regarding compliance with applicable laws and regulations.

Q How are Stim Products covered (i.e., under what health plan benefit category)?

A All Stim Products are considered durable medical equipment (“DME”) and are reimbursed under that benefit category.

Q Is it customary for physicians to provide and bill for Stim Products?

A No. Most physicians simply refer the patient to Orthofix, an accredited Medicare supplier with a reputation for high-quality service. Orthofix will coordinate the delivery, fitting, training and education for the patient, maintain the warranty, and will collect and file insurance paperwork for the patient. In addition, billing for DME is subject to federal laws and regulations, accreditation

requirements, and commercial payor restrictions—all of which can be onerous, expensive, and a distraction to a medical practice’s true focus. Most physician practices simply do not want to assume this administrative burden.

Q Are there any state laws that could affect my dispensing and billing for Stim Products?

A Possibly. There are at least 32 states that have enacted some form of self-referral prohibition. These statutes vary widely from state-to-state. If your state has a physician self-referral law, it could affect your provision of, and billing for, Stim Products. For example, some states require physicians to disclose certain financial relationships to their patients. We recommend that you consult with your state licensure board and your health care attorney to assess applicable state law requirements or prohibitions (if any).

Q Can I bill private health plans or other third-party payors (non-Medicare/Medicaid) for Stim Products?

A Yes, you may bill and obtain reimbursement for Stim Products from certain private health plans (and possibly workers’ compensation programs). As noted above, health plans cover and reimburse Stim Products under their DME benefit.

Please be advised, however, that some health plans may require that you be a credentialed participating DME supplier to bill for and collect reimbursement for these devices. Such plans conduct audits to verify the physician’s contract status and can deny payment (or recoup payments already made) for DME if the physician or physician’s group is not appropriately contracted as a network DME supplier.

In addition, there are laws in certain states that govern physician “self-referrals.” If your state has such as law, it could affect your provision of, and billing for, Stim Products.

If you wish to pursue direct billing for Stim Products, we recommend that you:

- Check with each health plan to identify any requirements that must be met to bill for and collect reimbursement for Stim Products.
- Consult with your health care attorney to assess compliance with applicable state laws (if any).

Q Are there general coverage criteria for Stim Products?

A Many health plans and other private insurers have medical policies and coverage criteria specific to Stim Products. We recommend that you check with the applicable health plan or payor to identify these coverage requirements.

Q What HCPCS codes should I use with health plans and other third-party payors for Stim Products?

A The following HCPCS codes are recommended for use with Orthofix Stim Products:

Product	HCPCS Code and Description
Physio-Stim	E0747 - Osteogenesis stimulator, electrical, noninvasive, other than spinal applications
Cervical-Stim	E0748 - Osteogenesis stimulator, electrical, noninvasive, spinal applications
Spinal-Stim	E0748 - Osteogenesis stimulator, electrical, noninvasive, spinal applications

Q I have been asked by a health plan to provide an invoice. Why is this necessary?

A While many health plans reimburse Stim Products based on a fee schedule, there are several plans that reimburse Stim Products on a cost basis (e.g., actual cost + X%). In these situations, the health plan requires the physician to submit the manufacturer’s invoice to determine reimbursement.

Q Do I have to collect copayments or coinsurance from patients?

A Health plan contracts commonly include provisions requiring the collection of coinsurance. The waiver of out-of-pocket obligations could violate the participation agreement with the plan. In one case (based on a theory that the health plan’s obligation to reimburse the provider is contingent on the patient’s obligation to pay), a court ordered a provider to repay to a plan all reimbursement made on behalf of enrollees whose copayments were waived.

Q Are there documentation requirements?

A Yes. Depending on the health plan, you may be required to submit and/or retain the following documentation: prescription order form, letter of medical necessity, x-ray reports, proof of delivery, and medical records. You are advised to check with the applicable health plan or payor to ascertain your documentation requirements.

